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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,073	04/08/2002	Brian Nielsen	P67699USO	6930

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EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,073	NIELSEN, BRIAN	
	Examiner	Art Unit	
	Kim M. Lewis	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5,6 and 8-13* is/are allowed.

6)☒ Claim(s) *1-4,7 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Summary

1. The amendment filed on 4/14/04 has been received and made of record. As requested the specification and claims 1-6 and 9-11 have been amended. Claims 14-23 have been added.

2. In response to applicant's remark regarding claim 14, on page 9, line 15, of the amendment, claim 14 has not been amended to depend from claim 12.

3. Claims 1-23 are pending in the instant application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claims 20-23, "the ratio of acid to chitosan" is indefinite in that the acid lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4, 8 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/4618 ("Court").

As regards claims 1, 4 and 19, Court discloses knitted wound dressings (wound care devices) comprising a mixture of swellable, gel forming chitosan fibers (abstract and page 4, line 31-page 5, line 25), which can form a coherent gel (page 4,lines 21-30). As to the absorption rate, note page 5, lines 26-30.

As regards claim 8, other fibers are used and are present within the claimed range (page 3, line 31-page 4 line).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2, 3, 7 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Court.

As regards claims 2 and 14-16 Court fails to teach the chitosan has a viscosity of 1000 cp, measured on a 1% w/w chitosan solution in 1% aqueous solution of acetic acid, that the chitosan has a viscosity of 500 cp, measured on a 1% w/w chitosan solution in 1% aqueous solution of acetic acid, that the chitosan has a viscosity of 300 cp, measured on a 1% w/w chitosan solution in 1% aqueous solution of acetic acid and that the chitosan has a viscosity of about 40 cp to about 200 cp measured on a 1% w/w chitosan solution in 1% aqueous solution of acetic acid. Absent a critical teaching and/or a showing of unexpected results derived from providing chitosan with the claimed viscosities, the examiner contends that the section of chitosan having the claimed viscosities would have been an obvious design choice to one having ordinary skill in the art.

As regards claims 3, 17 and 18,Court fails to teach that the proportion between length and diameter of the fibers is at least 25, that the proportion between the length and diameter of the fibers is more than 80, and that the proportion between the length and diameter of the fibers is more than 200. Absent a critical teaching and/or a showing of unexpected results derived from the use of fibers characterized in that the proportion between length and diameter of the fibers is at least 24, 80 and 200, the examiner contends that the selection of the length and diameter of the fibers is an obvious design choice dependent upon the intended use.

As regards claim 7, Court discloses that the fibers are manufactured into a knitted wound dressing. Court fails to explicitly state that the wound dressing is an island wound dressing. However, the examiner contends that one having ordinary skill in the art would have out of necessity constructed any type of wound dressing, island or otherwise, and such would have been an obvious design choice within the level of ordinary skill in the art.

11. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Court in view of EP 0627 225 A2.

As regards claims 20-23, Church fails to teach an acid. However, the applicant admits on page 2 of the specification that EP 0 627 225 A2 discloses a method for preparing a superabsorbent chitosan powder, being capable of absorbing liquid many times its own weight by forming a transparent gel. This is one by treating the powderous chitosan with an acid, preferably a hydroxy carbon acid like lactic acid or hydroxy butylic acid.

EP 0 627 225 A2 fails to teach chitosan fibers, however, the examiner contends that one having ordinary skill in the art would have discovered through routine experimentation that the absorbency of chitosan fibers of Church can also be increased by treating the fibers with an acid.

EP 0 627 225 A2 fails to teach the ratio of acid to chitosan is from 3 to 15 mmol of acid per gram of chitosan, that the ratio of acid to chitosan is from 4 to 10 mmol of acid per gram of chitosan, that the ratio of acid to chitosan is from 3 to 7.5 of acid per

gram of chitosan, that the ratio of acid to chitosan is from 3 to 15 mmol of acid per gram of chitosan.

Through routine experimentation, it would have been obvious to one having ordinary skill in the art to select the optimum ratio of acid to chitosan to provide the desired increased absorbency of the chitosan.

Response to Arguments

12. Applicant's arguments filed 4/14/04 have been fully considered but they are not persuasive. Applicant's attention is directed to the modified rejections.

13. In response to applicant's argument that Court is not enabling for a wound dressing as claimed and cannot be an anticipating reference, the examiner disagrees. Court anticipates the claimed invention as presently claimed as outlined in the rejection above, and the fact that Court only mentions chitosan once is irrelevant. The disclosure of Court allows for the use of chitosan fibers, which gel, swell, and are capable of maintaining their structural integrity on absorption.

Allowable Subject Matter

14. Claims 5, 6 and 8-13 are allowed.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
July 11, 2004